PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1212WOORD01	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/EP2004/051578	International filing date *(day/month/year)* 22.07.2004	Priority date *(day/month/year)* 23.07.2003
International Patent Classification (IPC) or national classification and IPC INV. A61K31/4439 A61P1/04		
Applicant ALTANA PHARMA AG		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in celectronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
25.01.2005	05.04.2006
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Collura, A Telephone No. +49 89 2399-

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/051578

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   Description, Pages

   1-16 as originally filed

   Claims, Numbers

   1-12 as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/051578

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 12 (with respect to IA)

because:

☒ the said international application, or the said claims Nos. 12 (with respect to IA) relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-12
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-12
Industrial applicability (IA)	Yes:	Claims	1-11
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item III.

Claim 12 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

Re Item V.

The following documents (D) are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: US-B1-6 410 569 (KOHL BERNHARD) 25 June 2002 (2002-06-25)
D2: US-A-5 693 818 (VON UNGE SVERKER) 2 December 1997 (1997-12-02)

For what concerns the most important passages of the above-mentioned documents, please see citations in the International Search Report, unless otherwise stated.

NOVELTY AND INVENTIVE STEP

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-12 is not new in the sense of Article 33(2) PCT.

a) Document D1 discloses pantoprazole magnesium dihydrate, its use for the manufacture of a medicament for the treatment of gastrointestinal diseases and the method for preparing said compound.
Said method consists of (a) adding a solution of $MgCl_2$ hexahydrate to a solution of pantoprazole Na sesquihydrate and (b) precipitating the solid compound.
D1 also teaches that the dihydrate of the magnesium salt of pantoprazole has surprising stability properties.
The subject-matter of claims 1-12, therefore, seems to be already anticipated by D1.

b) Document D2 describes the use of single enantiomers of omeprazole magnesium salt for the manufacture of a pharmaceutical formulation suitable for the treatment of gastrointestinal problems.

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According to what is disclosed in the description (col. 4, lines 11-34), the method for obtaining the claimed compounds comprises the following steps:

(i) separation of the two stereoisomers of a diastereoisomeric mixture of formula IV, in order to obtain the two enantiomers of omeprazole;

(ii) treatment of each single enantiomer obtained with NaOH in aqueous or non-aqueous medium;

(iii) treatment of the optically pure Na+ salts of omeprazole with $MgCl_2$ in aqueous solution.

Said method corresponds to the one used for preparing the compounds according to the present invention.

It is, therefore, not clear how, according to the present application, it would be possible to obtain alkaline salts which are different from those obtained according to the method described in D2.

Claims 1-4, 11 and 12 are, therefore, considered to not novel.

Claims 4-10 are referred to the magnesium salts of pantoprazole. Although D2 refers to the preparation of the magnesium salts of omeprazole, it would be obvious for the skilled person to apply such method to any compound with the falling into the same class of structures.

Thus, the subject-matter of claims 5-10 is not considered as involving an inventive step.

INDUSTRIAL APPLICABILITY

For the assessment of the present claim 12 on the question whether it is industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

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